

CLAIMS

1. A patch device adapted for use in the transdermal administration to a patient of a composition including, or consisting of, a selected irritating substance, the patch consisting of a layered construct adapted to be adhered to the skin of a patient and defining a depot cavity for the composition to be administered between a proximal layer and a distal layer thereof, which proximal layer is adapted in use to be located in intimate contact with the skin of the patient and which distal layer is in use disposed on the outer side thereof, the distal layer being characterised in that it is substantially impervious to the composition to be administered, and the proximal layer being characterised in that it is partially permeable to that composition, so that in use the composition may be disposed in the cavity and permeate from there through the proximal layer to be absorbed through the skin into the body of the patient, the proximal layer being further characterised in that its permeability to the irritating substance or component of the composition to be administered to the human or animal is less than the permeability of the human or animal skin, as the case may be, to such irritating substance or component.
2. The patch of claim 1 wherein the chemical composition of the proximal and distal layers are the same, and the respective permeability and impervious characteristics of the layers are achieved by virtue of the thicknesses of the respective layers.

3. The patch of claim 1 wherein the chemical composition of the proximal and distal layers are the same and the distal layer is modified by the application thereto of a thin impervious layer to render a composite layer which is impervious to the components of
5 the composition to be applied by means of the patch.

4. The patch of claim 1 characterised in that the layers are flexible and are produced from an elastomeric material.

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5. The patch of claim 4 in which the elastomeric material is a silicone material.

15 6. A patch according to claim 1 suitable for use in the administration of DMF to a patient and characterised in that the proximal layer of the patch has a permeability to dimethylformamide (DMF) such that DMF which is, in use, located in the cavity between the layers will be released through the proximal layer at a rate below the rate at which it is absorbed through the skin of the patient to which the
20 patch is in use applied, thereby substantially preventing build-up of DMF in direct contact with the skin of the patient.

25 7. The patch of claim 1 which is adapted to be adhered to the skin of the patient by having a peripheral edge zone of the proximal layer which is provided with a pharmaceutically acceptable adhesive layer, which adhesive layer is covered by means of a conventional peel-off cover sheet during storage.

8. The patch of claim 6 in which the layers of a patch intended to be used for the administration of dimethylformamide as such, or of a pharmaceutical preparation containing dimethylformamide as a penetration enhancing agent, are of the same chemical composition and are made from vulcanizates of silicone.

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9. The patch of claim 8 wherein the composition of the layer intended for use as the proximal layer in a patch for use in the administration of dimethylformamide (DMF) as such, or of a pharmaceutical preparation containing dimethylformamide as a penetration enhancing agent, is produced to have a permeability to dimethylformamide of not more than 9 mg DMF/cm²/hour.

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15 10. The patch of claim 1 in which the cavity defined between the proximal and distal layers of the patch construct is preferably in use filled with a solid filler material to serve as a carrier for the pharmaceutically active substance or composition to be received therein.

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11. The patch of claim 1 characterised in that it provides a passage through the distal layer or layers, through which passage the substance or composition to be administered to the patient may in use be introduced into the cavity of the patch after the patch had been placed on the patient.

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12. The patch of claim 11 wherein the passage is in part constituted by
a self-reclosing nipple or port formation integrally moulded with
the distal layer of the patch construct, or part thereof, to present
an access opening on the outer surface of the patch into which the
5 spout-like needle mounting of a conventional syringe may in use
be received to introduce the substance or composition to be
administered into the cavity via the passage.

13. The patch of claim 1 wherein the construct further includes a self-
10 adhesive mounting layer having a surface presenting a skin
adhesive which adhesive layer is typically during pre-use storage
of the product covered by a peelable cover layer, which cover layer
also overlies, and hence seals off, the proximal layer of the patch
construct until it is exposed by peeling off the cover layer.

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